

§ 20.25 Retroactive application of regulations.

The provisions of this part apply to all records in Food and Drug Administration files.

§ 20.26 Indexes of certain records.

(a) Indexes shall be maintained, and revised at least quarterly, for the following Food and Drug Administration records:

(1) Final orders published in the FEDERAL REGISTER with respect to every denial or withdrawal of approval of a new drug application or a new animal drug application for which a public hearing has been requested.

(2) Statements of policy and interpretation adopted by the agency and still in force and not published in the FEDERAL REGISTER.

(3) Administrative staff manuals and instructions to staff that affect a member of the public.

(b) A copy of each such index is available at cost from the Freedom of Information Staff (HFI-35), Food and Drug Administration, Room 12A-16, 5600 Fishers Lane, Rockville, MD 20857.

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981]

§ 20.27 Submission of records marked as confidential.

Marking records submitted to the Food and Drug Administration as confidential, or with any other similar term, raises no obligation by the Food and Drug Administration to regard such records as confidential, to return them to the person who has submitted them, to review them pursuant to the procedures established in § 20.44, to withhold them from disclosure to the public, or to advise the person submitting them when a request for their public disclosure is received or when they are in fact disclosed.

§ 20.28 Food and Drug Administration determinations of confidentiality.

A determination that data or information submitted to the Food and Drug Administration will be held in confidence and will not be available for public disclosure shall be made only in the form of a regulation published or cross-referenced in this part or by a

written determination pursuant to the procedure established in § 20.44.

§ 20.29 Prohibition on withdrawal of records from Food and Drug Administration files.

Except pursuant to the procedure established in § 20.44 for presubmission review of records, no person may withdraw records submitted to the Food and Drug Administration. All Food and Drug Administration records shall be retained by the agency until disposed of pursuant to routine record disposal procedures.

§ 20.30 Food and Drug Administration Freedom of Information Staff.

(a) The Office responsible for agency compliance with the Freedom of Information Act and this part is:

Freedom of Information Staff (HFI-35), Food and Drug Administration, Room 12A-16, 5600 Fishers Lane, Rockville, MD 20857.

(b) All requests for agency records shall be sent in writing to this office.

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981]

§ 20.31 Retention schedule of requests for Food and Drug Administration records.

(a) Unless unusual circumstances dictate otherwise, the Food and Drug Administration shall maintain and dispose of files of requests and responses furnished thereto within the time limits authorized by GSA General Records Schedule 14, FPMR 101-11-4, January 10, 1977, as follows:

(1) Files created by the receipt of and response to freedom of information requests, except denials and/or appeals, may be destroyed 2 years from date of final response.

(2) Files created by a freedom of information request which was wholly or partially denied may be destroyed 5 years after the denial letter was issued.

(3) Files created by a freedom of information request which was wholly or partially denied and which denial was subsequently appealed to the Department of Health and Human Services may be destroyed 4 years after final determination by FDA or 3 years after final adjudication by courts, whichever is later.

(b) This destruction schedule will automatically be revised whenever the time limits pertaining to these records are revised by the GSA General Records Schedule.

[47 FR 24277, June 4, 1982]

§20.32 Disclosure of Food and Drug Administration employee names.

The names of Food and Drug Administration employees will not be deleted from disclosable records except where such deletion is necessary to prevent disclosure of an informant or danger to the life or physical safety of the employee or under other extraordinary circumstances.

Subpart C—Procedures and Fees

§20.40 Filing a request for records.

(a) All requests for Food and Drug Administration records shall be filed in writing by mailing the request or delivering it to the Freedom of Information Staff (HFI-35), Food and Drug Administration, Room 12A-16, 5600 Fishers Lane, Rockville, MD 20857.

(b) A request for Food and Drug Administration records shall reasonably describe the records being sought, in a way that they can be identified and located. A request should include all pertinent details that will help identify the records sought.

(1) If the description is insufficient to locate the records requested, the Food and Drug Administration will so notify the person making the request and indicate the additional information needed to identify the records requested.

(2) Every reasonable effort shall be made by the Food and Drug Administration to assist in the identification and location of the records sought.

(c) Upon receipt of a request for records, the Freedom of Information Staff shall enter it in a public log. The log shall state the date received, the name of the person making the request, the nature of the record requested, the action taken on the request, the date of determination letter sent pursuant to §20.41(b), and the date(s) any records are subsequently furnished.

(d) A request by an individual, as defined in §21.3(a) of this chapter, for a

record about himself shall be subject to:

(1) The special requirements of part 21 of this chapter (the privacy regulations), and not to the provisions of this subpart, if the record requested is retrieved by the individual's name or other personal identifier and is contained in a Privacy Act Record System, as defined in §21.3(c) of this chapter.

(2) The provisions of this subpart if the record requested is not retrieved by the individual's name or other personal identifier, whether or not the record is contained in a Privacy Act Record System.

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981]

§20.41 Time limitations.

(a) All time limitations prescribed pursuant to this section shall begin as of the time at which a request for records is logged in by the Freedom of Information Staff pursuant to §20.40(c). An oral request for records shall not begin any time requirement. A written request for records sent elsewhere within the agency shall not begin any time requirement until it is redirected to the Freedom of Information Staff and is logged in there in accordance with §20.40(c).

(b) Within 10 working days (excepting Saturdays, Sundays, and legal public holidays) after a request for records is logged in at the Freedom of Information Staff, a letter shall be sent to the persons making the request determining whether, or to the extent which, the agency will comply with the request, and, if any records are denied, the reasons therefor.

(1) If all of the records requested have been located and a final determination has been made with respect to disclosure of all of the records requested, the letter shall so state.

(2) If all of the records have not been located or a final determination has not yet been made with respect to disclosure of all of the records requested, e.g., because it is necessary to consult the person affected pursuant to §20.45, the letter shall state the extent to which the records involved shall be disclosed pursuant to the rules established in this part.